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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,302	09/07/2006	Gad Alon	L&C UMB 710 US	9566
71385	7590	04/28/2008	EXAMINER	
LARCHER & CHAO LLP P.O. BOX 1666 SKOKIE, IL 60076			ROBINSON, JAMES MARSHALL	
			ART UNIT	PAPER NUMBER
			4148	
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			04/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,302	Applicant(s) ALON ET AL.	
	Examiner James M. Robinson	Art Unit 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 8,13,14,16,17,19,22,24-27 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,15,18,20,21,23,28 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/22/2006, 12/06/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. **Claim 5** is objected to because of the following informalities: Line 2 claims: --shin section, the lower leg portion spirals around at a least a portion of a--. In order to examine the claim, examiner interprets --shin section, the lower leg portion spirals around at least a portion of a--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. **Claim 10** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. The value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

Claim Rejections - 35 USC § 102

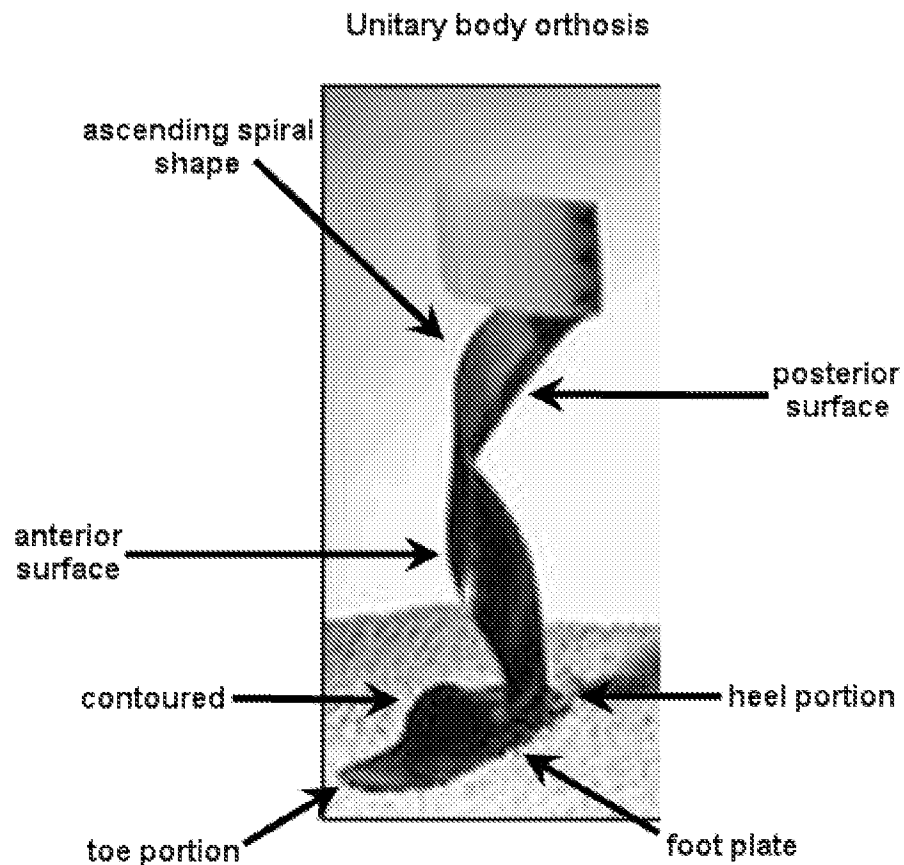
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-7, 12, 20-21, & 33** are rejected under 35 U.S.C. 102(a) as being anticipated by **John Michael's Corner [online] Retrieved from <http://www.oandp.com/news/jmcorner/2000-08/8.asp>**.

Regarding claim 1, Michael discloses an orthosis comprising a single, unitary body comprising: a generally spiral-shaped lower leg portion that, when the orthosis is worn, covers at least a portion of the anterior surface of the wearer's lower leg and at least a portion of the posterior surface of the wearer's lower leg; and a foot plate portion that, when the orthosis is worn, accepts the wearer's foot, wherein the lower leg portion is configured to spiral upward from the foot plate portion and make contact with an anterior surface of the wearer's lower leg prior to making contact with a posterior surface of the wearer's lower leg as the lower leg portion ascends (see fig. below).



Regarding claim 2, Michael discloses an orthosis wherein the foot plate portion comprises an anterior section; and a posterior section, wherein, when the orthosis is worn, the wearer's toes contact the anterior section and the wearer's heel contacts the posterior section, and wherein the foot plate portion is optionally contoured to complement at least a portion of the plantar surface of the wearer's foot so as to permit the wearer to wear shoes or sandals (see fig. above).

Regarding claim 3, Michael discloses an orthosis wherein: the unitary body is capable of transferring mechanical energy while the wearer is walking; the unitary body is capable of using the transferred mechanical energy to stop the wearer's knee from

hyperextending; and

the unitary body is capable of maintaining the wearer's foot in a position that allows the heel of the person's foot to contact the ground before the rest of the wearer's foot.

When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent.

Regarding claim 4, Michael discloses an orthosis wherein the lower leg portion comprises an ascending section that extends from the foot plate section and curves toward the anterior surface of the wearer's lower leg to form a shin section (see fig. above).

Regarding claim 5, Michael discloses an orthosis wherein, from the shin section, the lower leg portion spirals around at a least a portion of a lateral surface of the wearer's lower leg and transitions into a calf section (see fig. above).

Regarding claim 6, Michael discloses an orthosis wherein the calf section terminates in an upper end of the lower leg portion and begins to spiral back toward the anterior surface of the wearer's lower leg.

Regarding claim 7, Michael discloses an orthosis wherein the angle at which the lower leg portion spirals upward gradually decreases as the lower leg portion nears the calf of the wearer (see fig. above). The degree of the angle of the spiral at the calf is less than the degree of the angle at the shin. This change in the degree of the angle is gradual.

Regarding claim 12 Michael discloses an orthosis wherein the unitary body is made of composite carbon fiber (paragraph 1, line 3).

Regarding claim 20 Michael discloses an orthosis wherein the foot plate portion comprises a front edge and a back edge (refer to figure above), wherein the back edge is elevated above the front edge (the contour of the foot plate creates the elevation).

Regarding claim 21 Michael discloses an orthosis wherein the foot plate portion comprises a front edge and a back edge (refer to figure above), wherein the distance between the back edge and ground level is about twice the distance between the front edge and ground level (the contour of the foot plate creates the distance between the back edge and the ground level).

Regarding claim 33, Michael discloses an orthosis wherein the foot plate portion has a substantially flat outer surface (see fig. above).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 9-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over

John Michael's Corner [online] Retrieved from

<http://www.oandp.com/news/jmcorner/2000-08/8.asp> in view of Ingimundarson et al. (US 2005/0234378).

Regarding claims 9-11, Michael teaches a unitary body orthosis comprising an inner surface. Michael fails to teach an orthosis comprising a lining material attached to an inner surface; wherein the lining material is removably attached to the inner surface; wherein the lining material is removably attached to the inner surface using Velcro (hook and loop).

However, Ingimundarson teaches an orthosis comprising a lining material attached to an inner surface; wherein the lining material is removably attached to the inner surface; wherein the lining material is removably attached to the inner surface using Velcro (hook and loop) ([0056]).

To provide the device of the Michael reference with a removably attached lining surface would have been obvious to one of ordinary skill in the art, in view of the teachings of Ingimundarson, since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods (hook and loop integration) with no change in their respective functions. The combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e., one skilled in the art would have recognized that inclusion of a removable lining on the inner surface of the orthosis would serve to protect the user's lower leg from irritation caused by the carbon fiber inner surface rubbing on the tissue of the lower leg.

4. **Claims 15, 18, 23, & 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **John Michael's Corner [online]** Retrieved from <http://www.oandp.com/news/jmcorner/2000-08/8.asp>.

Regarding claims 15 & 18, Michael discloses an orthosis wherein the foot plate portion and the lower leg portion are disposed at an angle with respect to one another (refer to figure above).

Michael fails to disclose wherein the difference between the angle and 90 degrees is between about 7 degrees and about 14 degrees; wherein the difference between the angle and 90 degrees is between about 20 degrees and about 25 degrees.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the angle between about 7-10 degrees and 20-25 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. The range of the angle is obvious to ensure that a user when walking will strike the ground with his foot at the heel followed by the toe.

Regarding claim 23, Michael discloses an orthosis wherein the foot plate portion comprises an anterior section and a posterior section (refer to figure above) wherein a difference in elevation exists between the anterior section and the posterior section as a result of the contour of the foot plate.

Michael fails to explicitly teach the exact difference in elevation being between 0 cm and 3 cm.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the elevation difference between the anterior and posterior of the foot plate to be between 0 cm and 3 cm, since it has been held that

discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claim 28, Michael discloses an orthosis wherein the foot plate portion comprises a medial side and a lateral side having a difference in elevation as a result of the contour in the foot plate.

Michael fails to explicitly teach the difference in elevation between the medial side and the lateral side is greater than 0 millimeters and no greater than about 10 millimeters.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the elevation difference between the medial and lateral side of the foot plate to be between 0 mm and 10 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Patrick (US 20060270958), Smits (US 6887213), Willner (US 5897515), Lehneis (US 3680549), Wellershaus (US 20010027284), Andersen (US 6676618), Hall (US 5219324).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 7:30 AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James M. Robinson
April 21, 2008

/Terrell L Mckinnon/
Supervisory Patent Examiner, Art Unit 4148